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I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003903684 for a patent by ANADIS LTD. as filed on 16 July 2003.

I further certify that the above application is now proceeding in the name of ANADIS LTD and TATURA MILK INDUSTRIES pursuant to the provisions of Section 113 of the Patents Act 1990.



WITNESS my hand this
Twenty-third day of June 2004

A handwritten signature in black ink, appearing to be "L. Mynott".

LEANNE MYNOTT
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PROVISIONAL SPECIFICATION

**Invention Title: METHOD AND APPARATUS FOR COLLECTION OF
FLUIDS**

Applicant: ANADIS LTD.

The invention is described in the following statement:

METHOD AND APPARATUS FOR COLLECTION OF FLUIDS

This invention relates to a method and apparatus for the collection of small volumes of fluid from the teats of mammals, and to a milking system
5 incorporating such an apparatus and its use.

Background

A range of dairy-derived products can be made from secretions taken from the
10 mammary glands of mammals, such as cows, at a particular point in time or pursuant to the administration to the mammals of a particular course of treatment, or pursuant to the selection for milking, of a particular sub-category of animals within a larger herd. Examples include:

15 colostrum extract, which can be made from the mammary secretion of cows at a point in time shortly after parturition. In this case, the composition of the colostrum may change significantly as a function of milk volume within the first milking and also as a function of the number of milkings since parturition (generally less than 6);

20 hyperimmune colostrum extract, which can be made from colostrum taken from mammals which have been given a particular course of treatment, for example, a course of vaccinations against an antigen over a period of 3 months prior to parturition;

25 immune colostrum extract, which can be made from colostrum taken from a sub-category of animals that have been identified as carriers of particular antibodies of interest, for example antibodies with neutralising power against anthrax or Shiga toxin;

30 milk extract, which can be made from cows milk pursuant to the cows being fed a particular diet, for example a diet rich in particular antioxidants or essential oils; and

milk from animals that have been selected or genetically modified for their capacity to secrete a valuable substance such as a vaccine antigen.

5 Frequently the volume of the above secretions taken from the herd on a dairy farm for such purposes is significantly less than the volume of milk which is taken in the course of a routine milking. This is because few cows in the herd provide the desired secretions. This can give rise to a number of problems associated with collecting these secretions. The collection volume is often
10 insufficient to fill the milk lines of milking machines leading to contamination with out-of-specification material and/or unacceptable wastage.

The collection volume is also generally insufficient to fill standard milk vats, leading to poor refrigeration, the need to install customised vats to handle low volumes, and the need to arrange milk collection on a non-routine schedule. If
15 low volume reservoirs such as test buckets are used, contamination can readily occur between successive animals and the labour associated with adequate cleansing between animals is onerous. In particular it is generally necessary to remove the lid of the test bucket between animals, leading to the deposition of contamination in the harvested secretion. This problem is exacerbated by the
20 practice of locating the test bucket behind and beneath the rear end of the animals so that the buckets commonly become contaminated with faecal material. The problem of contamination is further exacerbated by the need to pour the secretions from the test bucket, which has a contaminated outside, into a separate storage container.

25 In the event that a modest volume of secretions is frozen prior to distribution to a processing facility, the depth of liquor frozen frequently exceeds 10 centimetres and in consequence, the process of freezing significantly diminishes the local homogeneity of the frozen secretion. This is problematic
30 when samples are taken for quality control, and leads to the need for expensive and inconvenient on-farm liquid sampling. Another problem arises when the freezing time becomes excessive.

Other methods which have previously been used to collect small volumes of secretions from the mammary glands of mammals include hand milking into a small reservoir. This is an impractical collection method as it significantly disrupts the routine of a busy commercial dairy.

5

Another method is drip sampling into a herd test sampler. In this case a small amount of sample corresponds to a larger volume of milk running through the milking machine. This method does not permit the collection of a small volume of a high value secretion.

10

Another option is to construct a customised vat with a preset batch volume limit (eg 150 litres – this may be considered the minimum acceptable volume for pick-up by a tanker). The difficulties associated with this method include the high set-up cost and significant wastage.

15

US Patent 5,913,281 describes a method for separating the foremilk from the milk yield. An auxiliary reservoir is provided between the teat cups and the main milk vat. The foremilk is diverted into the reservoir at the commencement of the milking process. This method is not suitable for harvesting the low volume component which may not substantially reside in the foremilk.

20

Summary

The invention provides an apparatus for use with a milking machine comprising one or more teat cups and a vacuum source providing a vacuum in the teat cups, for collecting a small volume of liquid for cold storage, the apparatus comprising:

25

- a fluid collection receptacle having an opening for collecting fluid;
- a housing for the fluid collection receptacle comprising an inlet for receiving the liquid from the one or more teat cups and a port for providing a vacuum within the housing from said vacuum source; and
- means for retaining the opening of the receptacle to receive liquid via the housing inlet.

30

The fluid collection receptacle is preferably a flexible bag.

5 The housing inlet for receiving the liquid from one or more teat cups preferably comprises a conduit protruding into the housing and means for retaining the receptacle (particularly a flexible bag) so that the receptacle is retained about the opening of the inlet to receive fluid therefrom.

10 In a particularly preferred embodiment the receptacle is a flexible fluid collection bag comprising a collar defining the opening. The collar may be a resilient semi-rigid collar for receiving a closure for sealing the bag for cold storage. In this embodiment the housing inlet preferably comprises a conduit extending into the housing and said means for retaining the bag cooperates with the collar to retain the collar so that the inlet extends into the flexible bag through the opening. This embodiment is particularly advantageous as it allows efficient
15 safe collection of clean product and yet is relatively inexpensive and convenient to operate. In contrast to the collection receptacle which is preferably flexible the housing is preferably rigid whereby the vacuum is transferred to the inlet.

20 The flexible bag typically has a volume of at least 500 ml when filled with liquid and preferably is a lay flat bag providing a width of no more than 10 cm when filled with liquid and placed on a flat surface. More preferably the width of the bag is no more than 5 cm when filled with liquid and placed on a flat surface.

25 The housing will generally comprise a top wall a side wall and bottom wall. The housing preferably comprises a lid portion comprising the top wall and a body portion comprising the side wall and bottom wall. The lid portion preferably comprises said fluid inlet and said port for providing a vacuum. In this embodiment the lid portion preferably comprises a conduit for receiving liquid extending down from said top wall to provide an inlet port spaced down from the
30 top wall. Retaining means may be provided, for example on an outer wall of the conduit, for cooperating with a collar of the flexible bag so that the flexible bag receives liquid from the inlet.

The collar may be provided with a flange (or other means) for engaging the retaining means. The lid portion is preferably provided with an inlet filter in line with the housing inlet for removing solids from the liquid drawn into the housing inlet by a vacuum applied to said port.

5

The filter may be partly integral with the housing lid. The filter or portion thereof may be integral with the inlet conduit particularly the up stream end of the inlet.

10

In a further embodiment the invention provides a milking system comprising an apparatus for collecting a small volume of liquid such as colostrum, the system comprising:

15

- a plurality of teat cups;
- a vacuum source for applying a vacuum to the teat cups for collecting liquid;
- a container for collecting relatively large volumes of milk; and
- an apparatus as described above for collecting relatively small volumes of liquid.

20

The milking system will typically also include a pressure oscillation means for providing pulsating vacuum to the teat cups and a vacuum line downstream of the apparatus for collecting relatively small volumes of liquid.

25

The milking system may comprise a multiplicity of milking stations including at least one station for delivering small volumes of liquid to the apparatus of the invention as hereinbefore described.

30

In yet another embodiment the invention provides a method of collecting a small volume of liquid such as colostrum from the mammary glands of mammals such as cows comprising:

- collecting secretions in a flexible bag;
- sealing the opening in the bag.

Preferably the flexible bag comprises a pocket to allow sampling of the bag contents.

The secretions (particularly colostrum) are preferably collected shortly after parturition. Our copending patent applications PCT/AU03/00348 and PCT/AU03/00616 describe products such as colostrum and hyperimmune colostrum which may be collected using the apparatus of the invention.

5

In accordance with a further aspect the invention provides a flexible bag for collection of a fluid and providing a sample of the bag contents, the bag comprising a bag body for receiving a liquid via an opening and a sampling pocket (preferable integrally formed with the interior of the bag) separated from
10 the interior of a main body of the bag by an elongated seal the pocket comprising an entrance for receiving liquid from the interior of the main body of the bag. The sampling pocket is preferably divided from the main body of the bag by an elongated seal between the opposed wall portion of the bag. The elongated seal together with the portions of the bag wall (and optionally also
15 one or more further elongated seals) define the entrance to the pocket which provides a passage between the interior main body and the pocket for allowing a sample of the bag contents to be forced into the pocket after the bag opening is sealed.

20 In a preferred embodiment the bag comprises two or more opposed sheet portions sealed together. The sheet portions may be separate sheets joined by a peripheral seal or portions of a folded sheet or tube sealed at either end. Typically the pocket is formed by an interrupted elongate seal extending between two parts on the periphery of the bag the interruption providing an
25 entrance to the pocket. It is particularly convenient where the bag is four sided for the interrupted seal to extend across intersecting edges to form a pocket at one corner.

Typically the pocket will have a volume of no more than 5% of the total volume
30 of the flexible bag.

In the case of a lay flat bag the area of the pocket in the lay flat condition is typically no more than 5% of the bag. Typically the area of the bag when flat (ie one face) is from 10,000 mm² to 1 m².

The bag of the invention is preferably generally rectangular when flat with the pocket being formed adjacent one end. The opening of the bag is preferably closer to the end in which the pocket is formed so that when the bag is retained about the inlet of the fluid collection receptacle the pocket is in the upper part of the bag and fluid is collected in the lower part of the bag.

It is generally preferred that the inlet of the bag is spaced below the pocket opening to the main body of the bag.

10

The sample may be taken from liquid collected in the bag by a relatively simple procedure. The bag will generally be sealed and the contents of the bag agitated to thoroughly mix the liquid and ensure the sample is representative of the contents. To fill the pocket liquid may then be distributed onto the seal defining the pocket and forced through the opening of the pocket from the interior of the main body of the bag. The contents of the bag and pocket may subsequently be frozen and the sample in the pocket removed by breaching an outer wall when the bag is formed with a rectangular seal the sample may be removed by breaching the seal. A clip may be applied to the outside of the bag to seal the opening of the pocket from the interior of the bag body before freezing. A suitable clip is of the type for clipping flexible sheets together comprising a resilient outer member of C-shaped cross-section and a cylindrical inner member received within the outer member with the flexible sheets there between. The outer member has longitudinal edge portions joining C-shaped ends.

25

The opening of the pocket to the interior of the main bag is generally provided by a interruption of the seal which is of dimensions of from 1 mm to 50 mm and preferably 2 mm to 20 mm.

30

The flexible bag used in the method is preferably a lay flat bag having a collar and a fill volume of at least 500 ml.

Detailed Description

An embodiment of the invention will now be described with reference to the attached drawings.

5

Figure 1a shows an apparatus in accordance with the invention without the fluid receptacle;

Figure 1b shows the lid of an apparatus of Fig 1a with detail of the underside;

10

Figure 1c shows a fluid collection bag attached to the inlet conduit of the apparatus of Figure 1a;

Figure 1d shows a schematic cross section of an alternative inlet conduit arrangement;

15

Figure 2 is a schematic diagram showing a conventional milking system with collection for three cow stations shown; and

Figure 3 is a schematic drawing of a station from a milking system of Figure 2 which has been modified with the apparatus of the invention for collection of small volume of mammary secretion such as colostrum at cow station 1.

20

Figure 4 shows a fluid collection bag comprising a sampling pocket in accordance with one aspect of the invention.

25

Figure 4a is a part cross-section of the bag of Figure 4 along the dotted line 4a-4a.

Figure 5 is a clip which may be used to close the opening in the sample pocket.

30

Figure 6 is an expanded view of the clip of Figure 5 located over the opening in the sample collection pocket of the bag of Figure 4.

Referring to the drawings, Figure 1a, 1b and 1c show an apparatus of the invention comprising a housing (1) and flexible bag (10). The housing (1) comprises lid portion (2) optionally provided with a handle (2a) and body portion (3).

5

The body portion comprises a side wall (4) a bottom wall (5) and an upper end (6) of the side wall (4) for cooperating with and forming a seal with the periphery (7) of the underside of the lid (2). The underside (8) of the lid (2) inboard of the periphery (7) forms a top wall of the housing (1). The outer side (9) of lid (2) is provided with a vacuum port (11) for connection to a vacuum line for placing the housing (1) under vacuum.

10

The lid is further provided with a liquid inlet conduit (12) ending in an inlet port (13) within the housing (1) which is spaced below the underside (8) of the lid (2). The inlet conduit (12) is provided with a retaining means (14) for retaining a flexible bag (10). Flexible bag (10) comprises a bag body (15) formed of a flexible plastics material such as a polyolefin, polyester, suitable laminate or the like (such as are known in the art for storage of liquid food products) and a semi-rigid collar (16) providing an opening (17) for the bag. The collar (16) has an outside (18) provided with a flange (19) which cooperates with the retaining means (14) to locate the collar about the inlet conduit (12) with the inlet port (13) located within the flexible bag (10). The flexible bag body (15) is preferably a lay flat bag which when filled with liquid and placed on a flat surface is less than 5 cm thick. It preferably has a capacity of at least 500 ml and more preferably from 500 ml to 50 litres.

15

20

25

The vacuum applied to the vacuum port (11) is transferred to the inlet conduit (12) via the opening (17) in the bag (10) (as shown in Figure 1c) or by other suitable means such as the arrangement shown in Figure 1d where a pressure equalising port (20) is provided in the conduit (12) and an internal conduit (21) is provided for transferring liquid below the port (20) to prevent liquid being sucked out of the pressure equalising port (20). When a pressure equalising port is present the collar (16) may be sealed about the inlet conduit (12). Upstream of

30

the inlet conduit is a filter (22) which is connected with the top (or outside) (9) of the lid (2) and may be partly integral with the lid (2).

5 The underside (8) of the lid (2) may be provided with means for preventing the flexible bag (10) from blocking the vacuum port (11) such as a cage (11a) as shown in Figure 1b.

10 The filter generally has a filter housing (23) with an inlet (24) for receiving liquid upstream of the inlet conduit (12) and filter elements (not shown) such as filter disks or filter sock of a type known in the art.

15 Referring to Figure 2 a milking machine of a type known in the art is shown which comprises a number of cow stations (25a, 25b, 25c) each comprising a multiplicity of teat cups (generally four) provided with a pulsing vacuum line (26) provided with pressure oscillation means (27a, 27b, 27c) at respective stations (25a, 25b, 25c) to provide interrupted vacuum from the vacuum source to withdraw milk from the teats. Milk withdrawn is transferred to a milk vat by liquid transfer line (28) which is under vacuum at the downstream end.

20 Figure 3 shows a system of the invention provided with an apparatus described above with reference to Figures 1a, 1b and 1c for collecting relatively small volumes of milk from each cow milked at the first station (25a). The volume is relatively small compared with the milk collected by the milking system.

25 The inlet (12) of the apparatus of the invention (1) is joined by line (31) to the teat cups at the first station (25a). The vacuum port (11) of apparatus (1) is connected to a vacuum line (28) to provide a reduced pressure within the housing and draw fluid from the first cow station (25a) into the bag (15).

30 In order to facilitate the taking of a representative sample of liquid once the contents of the bag have been frozen a clip may be applied across a section of the bag containing collected liquid such as a corner portion to form a sample appendix prior to freezing for removal after freezing. The clip may be in the form of a tube member having an elongated slot for receiving a section

extending across the bag to define the appendix and an elongated member for retaining the section of bag within the tube so as to close off the bag and form said appendix portion.

5 A particularly preferred flexible bag construction constitutes the further aspect of the present invention. The bag which will now be described with reference to Figures 4 to 6, while particularly useful in conjunction with the collection of vessel of the present invention, may be used in other collection apparatus or for storage and sampling. Figure 4 shows an empty bag (10) in accordance
10 with this aspect of the invention. The bag (10) is formed of two sheets of thermoplastic material (see Figure 4a). The thermoplastic sheets (30, 31) are joined by a heat seal at the periphery (32) of the bag (10) and the interior is divided into a main body interior (33) which is provided with an opening (17) to the outside of the bag for collection of liquid. The interior of the bag
15 also comprises a sample collection pocket (34) separated from the main body of the bag (33) by a longitudinal seal (35) which is interrupted to define the opening (36) of the pocket (34) to the main body of the bag interior (33). The pocket opening (36) provides a passage for transferring a liquid from the interior of the main body of the bag (33) to the sampling pocket (34).

20 The pocket is located adjacent one end of the bag (37) and the opening (17) of the bag (10) is generally closer to the same end (37) than the remote end (38). Liquid is collected through the opening (17) by suspending the bag (10) from the mouth (16) defining the opening (17) (see Fig 1c) and accordingly
25 the end adjacent the pocket (37) is the upper end of the bag during liquid collection. Liquid therefore collects in the remote end (38) and fills toward the opening (17). When the required volume of liquid has been collected the bag is removed from the inlet (13) of the collection apparatus (1) and a cap (39) is applied to provide a liquid tight seal.

30 During collection of a complex liquid such as milk, components of the liquid such as fat or the like may separate from the liquid. To collect a representative sample, the liquid is agitated to form a homogeneous mixture and the bag oriented so that the liquid is adjacent the seal (35) defining the

opening (36) of the pocket (34) to the main body of the bag interior (33). Pressure is applied to the liquid to force a sample through the pocket opening (36) and provide a suitable volume of sample within the pocket (34).

5 In order to facilitate the maintenance of good seal within the bag and isolation of the sample, a clip (40) is preferably used as shown in Figure 5. The clip (40) has two components including a first and outer member (41) comprising a C-shaped cross-section (43) and longitudinal edges (44). The first member (41) is resilient enabling it to admit the second component (42) which is
10 generally cylindrical. The components form a clip by locating the flexible materials to be clipped about the inner member (42) and locating the inner member within the outer member (41) with the clipped flexible material therebetween.

15 Figure 6 shows exploded view of the seal separating the pocket and main body of the bag in which the interruption (36) of the seal (35) as shown in Figure 4 has been closed by a clip (40) of the type shown in Figure 5.

The liquid such as milk may be frozen for storage in the bag. A
20 representative sample located in the pocket (34) may be removed without disturbing the main body of frozen liquid in the main body of the bag (33) by bridging the peripheral seal or wall of the bag within the pocket and removing the frozen sample. In the illustrated example the pocket sample will be of triangular or wedge shape.

25

The bag of the invention allows liquid to be conveniently sampled with a minimum disruption and without compromising the liquid collected.

30 One aspect of the invention is also demonstrated in the following non-limiting example.

Example

A bag comprising a pocket as described with reference to Figures 4 to 6 was used to collect colostrum from a commercial milking operation with the apparatus of the invention as depicted in Figures 1 to 3.

5

Following collection of colostrum the bag was removed from the fluid inlet and housing and the opening sealed. The contents of the bag was agitated by kneading the bag without forcing liquid into the pocket. After the contents had been mixed thoroughly the liquid was forced into the pocket at the top of the bag.

10

Four bags of colostrum were collected and samples of liquid were taken from the main body of the bag and from the sample pocket in each case and compared in the table below.

15

<u>Pocket Sample</u>	Fat B	Protein	SNF	Cells
1	2.4	21.7	26.04	1566
2	3.6	14.46	19.44	854
3	3.04	8.82	14.4	2242
4	3.9	16.88	21.4	6534
<u>Bag Sample</u>				
1	2.58	24.38	29.16	1720
2	3.54	14.83	19.94	866
3	2.92	9.04	14.74	2230
4	4.18	16.7	21.12	6708

SNF - Solids Non-Fat

The pocket was found to provide a good representative sub-sample of the bag contents.

20

Finally, it is understood that various other modifications and/or alterations may be made without departing from the spirit of the present invention as outlined herein.

5 DATED: 15 July, 2003
PHILLIPS ORMONDE & FITZPATRICK
Attorneys for:
ANADIS LIMITED

David B Fitzpatrick

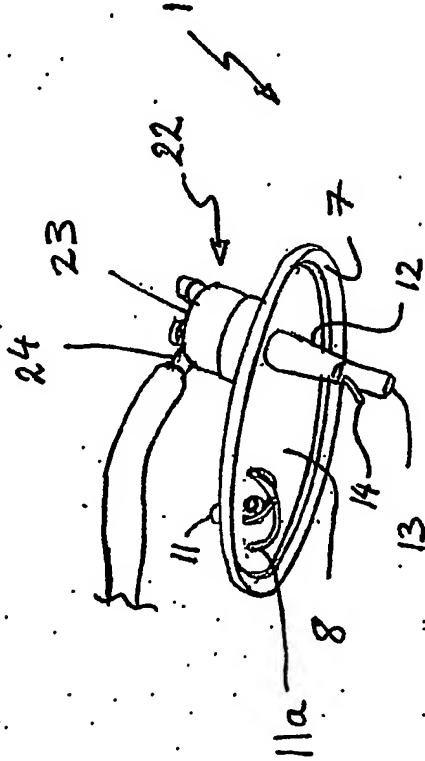


Figure 1b:

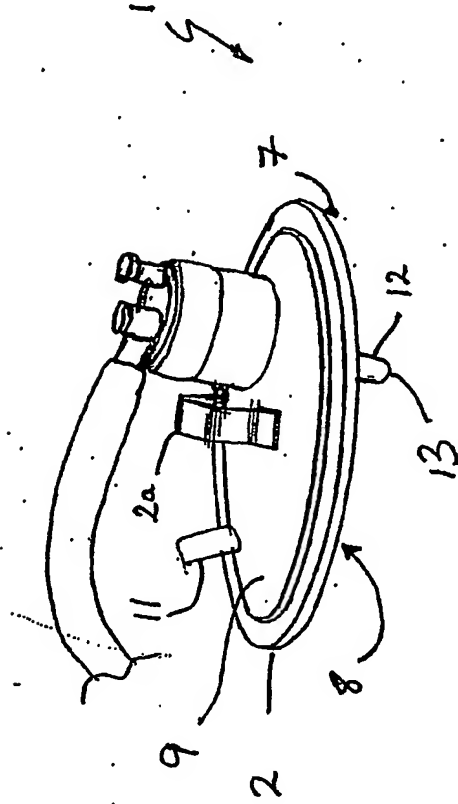
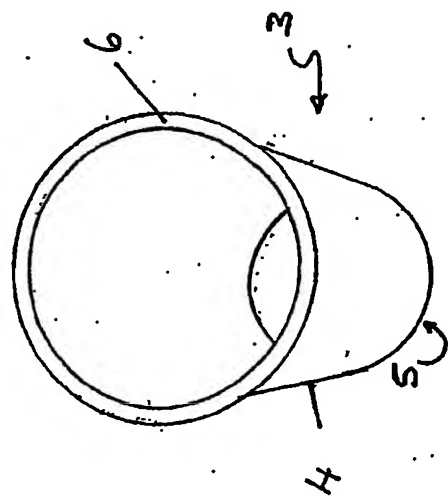


Figure 1a:



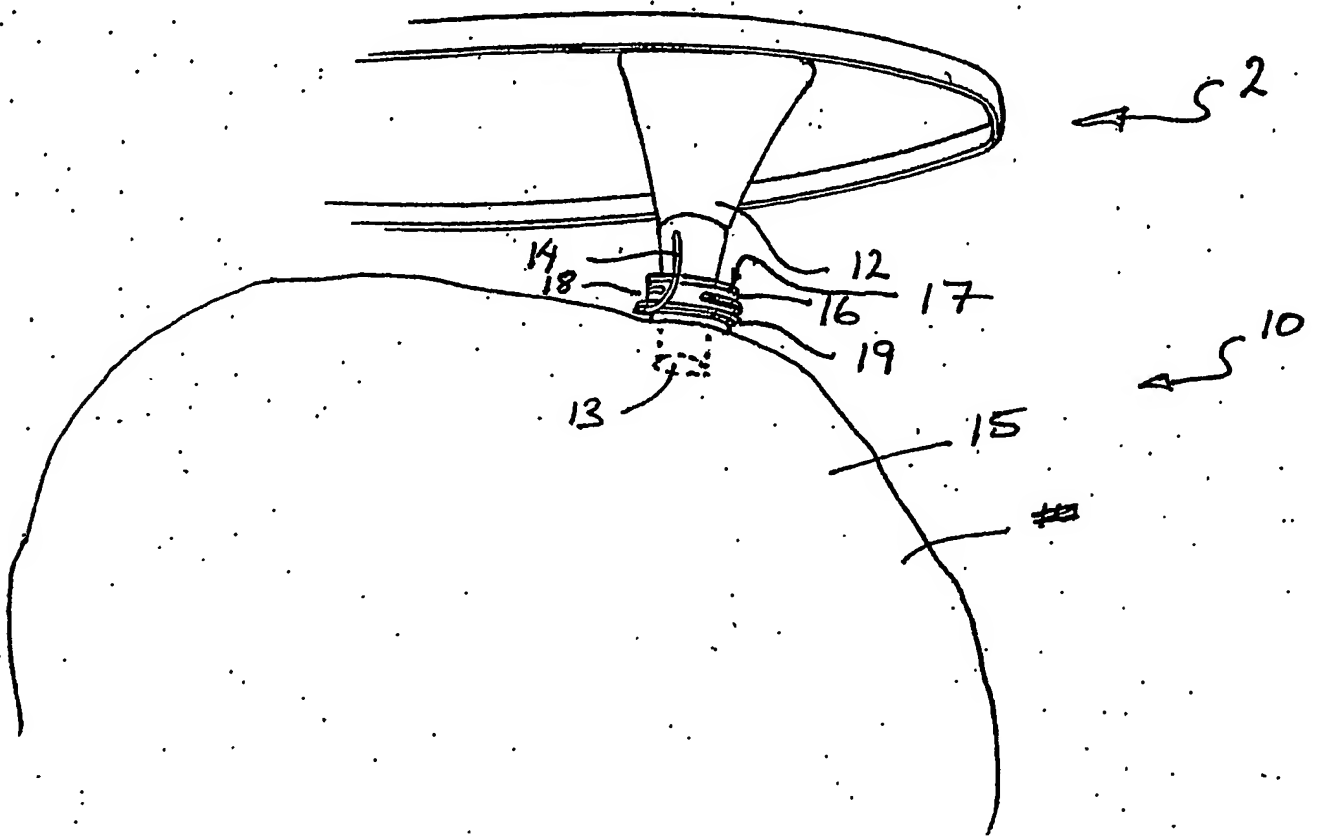


Figure 1c

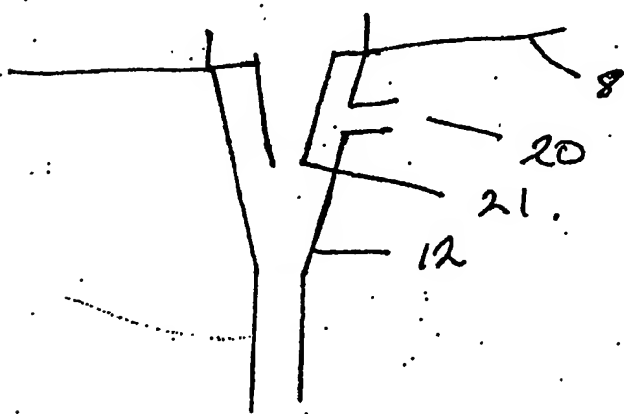


Figure 1d

Ordinary system

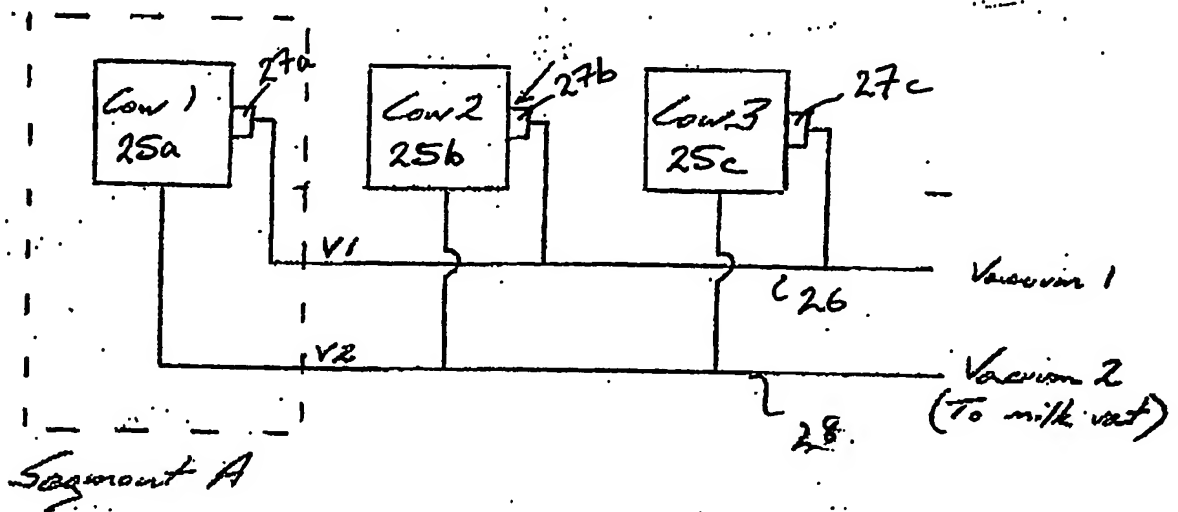


Figure 2

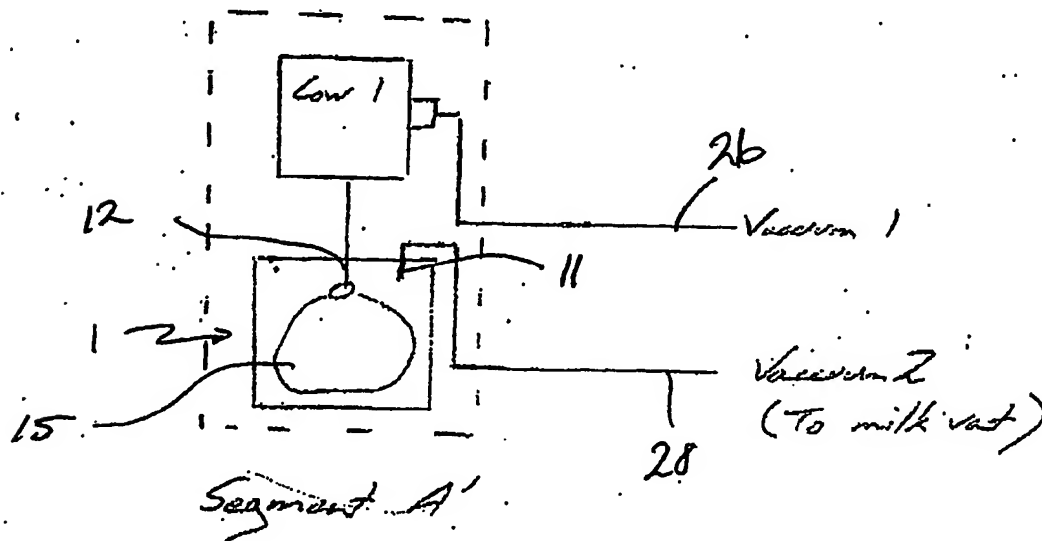


Figure 3

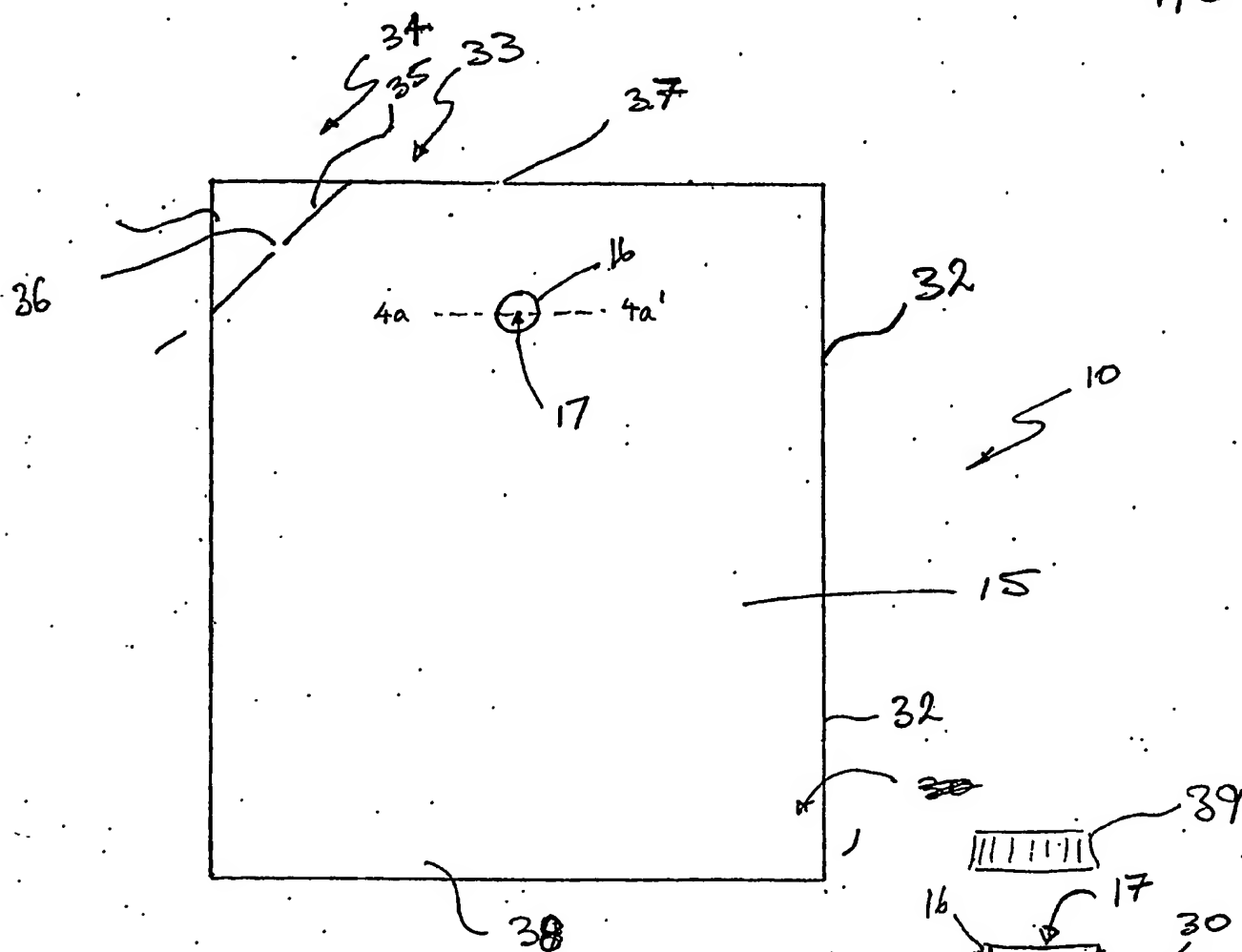


Figure 4

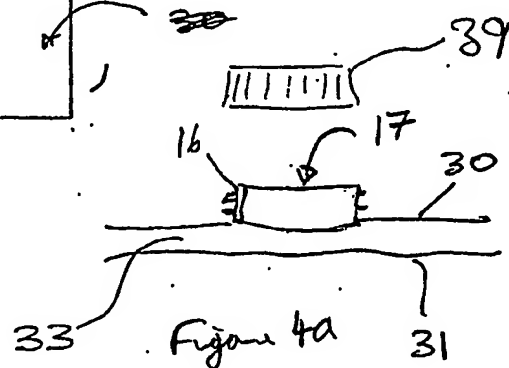


Figure 4a

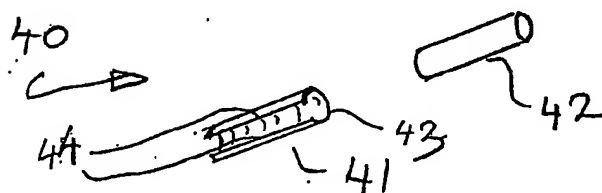


Figure 5

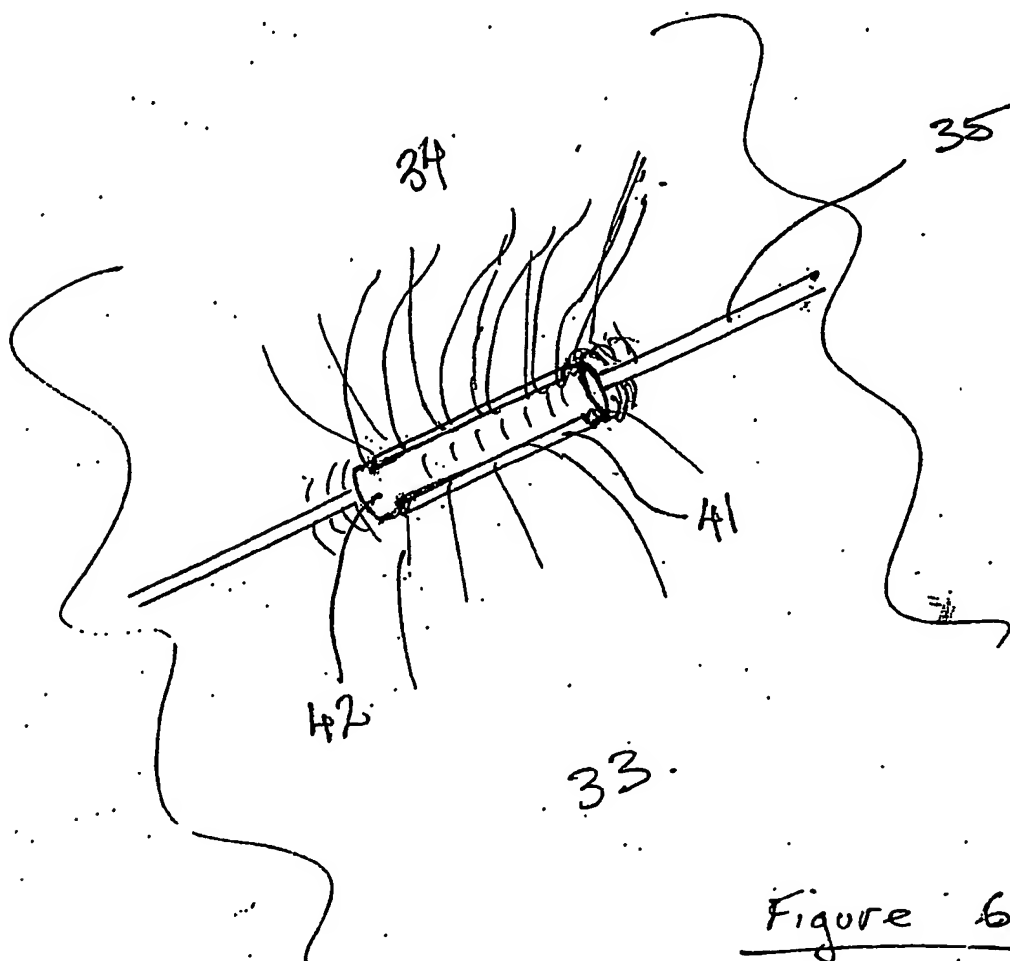


Figure 6

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